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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,774	07/25/2001	Manaud Pierre Frederic De Raspidé	PC10915A	5154
28880	7590	05/23/2005	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/912,774	DE RASPIDE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-25, 27-37 and 40-42 is/are pending in the application.  
     4a) Of the above claim(s) 27-37 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-10, 16-25 and 40-42 is/are rejected.  
 7) ☒ Claim(s) 11-14 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*PD*

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### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, power of attorney, declaration under 37 CFR 1.132, amendment and claims, all filed 02/22/05. Claims 1-14, 16-25, 27-37 and 40-42 are pending.

#### **New claims identified as Original Claims:**

Claims 27-37 are identified as original claims. However, examination of these claims in comparison with the same set of claims originally filed and subsequently submitted as original in the submissions of 08/20/03 and 03/16/04 shows that these claims are different.

Thus newly submitted claims 27-37 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons given above. And since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. It will also be noted that because claims 32-37 were previously rejected under 35 USC 112, first paragraph, that rejection is maintained below since the prevention language remains with the claims. But the claims 27-37 represent new claims and are withdrawn from consideration.

### ***Drawings***

Applicants indicate that corrected drawings will be provided when allowable subject matter is recognized. However, the objection to the drawings will be withdrawn upon submission of corrected drawings. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

1. Claims 32-37 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the recurrence of migraine, does not reasonably provide enablement for preventing migraine recurrence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants state that it is well known prior to the priority date of the examined application that eletriptan is useful in the prevention of migraine occurrence and that the specification of WO 00/06161 at page 1, lines 16 and 17 demonstrates that eletriptan is useful not only in the treatment of migraine but also in the treatment of migraine recurrence. Applicants request the removal of the first paragraph rejection.

2. The 112 first paragraph rejection is maintained and applicants' arguments filed 02/22/05 have been fully considered but they are not persuasive. Examiner appreciates applicants' statement that "eletriptan is useful not only in the treatment of migraine but also in the treatment of migraine recurrence" and the issue is not in treating but in prevention of the migraine or migraine recurrence. The standard for prevention is high and applicants have no showing of predictable data where the migraine recurrence is prevented in all the cases at all the times.

3. The rejection of claims 15, 16, 20-26, 38, 39 and 42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment filed 02/22/05.

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4. Claim 19 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Applicants' arguments filed 02/22/05 have been fully considered but they are not persuasive. Examiner agrees with applicants that claim 19 properly depends from claim 1 and the rejection was not that claim 19 improperly depends from claim 1. The issue is that the permeable coating in claim 1 consists of one or more acrylic copolymers and as such the talc and triethyl citrate are excluded from the permeable coating. Also the optional inclusion of anti-tacking agent or wetting agent or plasticizer does not include those excipients in the permeable coating. It is suggested that the "optional" term be removed from claim 1 if the permeable coating has to include the wetting or anti-tacking or plasticizer agents. In this respect, claim 1 would read ...permeable coating consisting of ... and one or more ....

***Claim Rejections - 35 USC § 102***

6. Claim 40 remain rejected under 35 U.S.C. 102(a) as being anticipated by Jackson et al. (WO 00/06161).

Applicants say that claim 40 is canceled and the rejection is thus moot.

The rejection is not moot because claim 40 remains pending in the application.

7. Claims 1, 4 and 40-42 remain rejected under 35 U.S.C. 102(e) as being anticipated by Cherukuri et al. (US 2002/0044962).

Applicants argue that the polymer of Cherukuri is erodible while the polymer of the instant claims is "water-insoluble" and therefore, this difference accords patentable distinction of the instant claims over Cherukuri.

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8. Applicants' arguments filed 02/22/05 have been fully considered but they are not persuasive.

Cherukuri discloses EUDRAGIT RS, which is the polymer of the instant claims. Thus, on this basis, Cherukuri discloses each and every element of the claims. It is further noted that if the original claims 27 and 32 are re-presented, the rejection of 08/23/04 will be applicable.

***Claim Rejections - 35 USC § 103***

9. Claims 1-10, 16-25 and 40-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Stevens et al. (US 5,112,621).

Applicants say that according to the experimental evidence conducted, the coating composition of Stevens applied to the eletriptan of Jackson, does not produce sigmoidal pattern of drug release.

10. Applicants' arguments filed 02/22/05 have been fully considered but they are not persuasive.

Applicants' experimental data provided in **132 declaration** prepares the drug eletriptan by layering the drug cores onto sugar spheres and this aspect differs form the prior art of Jackson. Thus, applicants' composition in the declaration differs form the Jackson composition. Also contrary to applicants' statement that ethyl cellulose is required in Stevens, it is respectfully noted that there is a disclosure of a formulation having EUDRAGIT as the sole polymer. Specifically, Stevens in column 3, lines 8-17 states:

“the dissolution of uncoated microparticles (containing only the active principle, especially diltiazem) is pH-dependent, the dissolution of microparticles coated with ethyl cellulose is pH-dependent, the dissolution of microparticles coated with Eudragit RS is pH-dependent, the

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dissolution of microparticles coated with an ethyl cellulose/Eudragit RS mixture, in proportions of from 40:60 to 60:40, is pH-independent.” Thus EUDRAGIT coated formulation is disclosed.

It is also noted if original claims 27-37 are re-presented, the rejection of these claims over Jackson in view of Stevens will be maintained.

11. Claims 1-10, 16-25, 41 and 42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (WO 00/06161) in view of Cherukuri et al. (US 2002/0055962).

Applicants argue that Cherukuri disclose erodible polymers while the instant claims are directed to water-insoluble polymers.

12. Applicants' arguments filed 02/22/05 have been fully considered but they are not persuasive.

Cherukuri disclose EUDRAGIT RS and EUDRAGIT RS is water-insoluble

It is also noted that if original claims 27-37 are re-presented, the rejection of these claims over Jackson in view of Cherukuri will be maintained.

13. Claims 11-14 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The presentation of claims 27-37 as original claims when in fact they are new claims leads to the withdrawal of the claims.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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